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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,999	12/14/2005	Rodney James Lane	207.005	3576

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Abelman Frayne & Schwab
666 Third Avenue
10th Floor
New York, NY 10017-5621

EXAMINER	
WIEST, PHILIP R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
11/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,999	LANE ET AL.	
	Examiner	Art Unit	
	Phil Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-57* is/are pending in the application.

4a) Of the above claim(s) *28-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II in the reply filed on 9/24/08 is acknowledged. The traversal is on the ground(s) that any prior art search for a device connected to the venous and arterial systems would be within the same general search. This is not found persuasive because devices having outlets connected to the venous and arterial system have distinct modes of operation and therefore require a different search. The requirement is still deemed proper and is therefore made FINAL. Group I: Claims 1-27 have been voluntarily cancelled by applicant.

Additionally, applicant has voluntarily withdrawn Group II: Claims 28-38 and replaced them with newly added claims 39-57. Claims 39-57 have been examined on the merits.

Claim Rejections - 35 USC § 112

2. Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim does not point out exactly what is meant by a *relatively* flat flow pressure curve characteristic. The specification and figures do not provide examples of what s meant by "relatively flat."

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 39-42 and 44-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Viole et al. (US 6,610,004).

5. With respect to Claims 39-42, 44, 45, 47-54, and 56, Viole et al. (hereafter 'Viole') teaches an implantable heart assist system for perfusing a distal region of a patient's circulatory system comprising a blood pump 32 in fluid communication with the circulatory system. The pump may be an implantable centrifugal pump, which is capable of pumping blood such that a localized hypertensive region will be created in a distal region downstream of the pump. The pump is capable of providing a continuous, suprasystolic pressure thereby reducing hemodynamic load on the left ventricle. The pump is located in a position remote from the heart of the patient (see Figures 1-14), such that blood is pumped to an arterial distal region of the circulatory system, such as the femoral artery in a patient's leg (for example, see Figure 11). Additionally, Viole teaches that the pump is capable of delivering either a constant or pulsatile mean blood pressure (see Abstract and entire disclosure). Therefore, the pump is capable of delivering a constant pressure to the distal area, such that the pump has a relatively flat flow pressure curve characteristic. The pump has an inlet and an outlet, both the inlet and outlet being connected to the arterial system (for example, see figures 2 and 11).

The inlet and outlet of the pump are both attached to cannulae of varying length, such that the blood pump is capable of being attached to a plurality of different arteries (see figures). The implantable blood pump is connected to an implantable power source 44, a motor 40, and an implantable controller 42

6. With respect to Claims 46 and 55, the controller is programmed to control the output of the pump, and therefore is fully capable of restricting flow through the device (i.e. functioning as a flow restrictor) (Column 12, Lines 6-27). Additionally, the controller may be disposed outside the body, such that the system is able to be controller externally (Column 12, Lines 28-38).

7. Claims 39-49 and 51-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Moulder (US 5,267,940). Moulder teaches a blood pumping system comprising a centrifugal pump in fluid communication with the circulatory system, wherein the pump is capable of pumping blood such that a localized hypertensive region will be created in a distal region downstream of the pump. The centrifugal pump is capable of providing a continuous, suprasystolic pressure thereby reducing hemodynamic load on the left ventricle. The pump is located in a position remote from the heart of the patient, such that blood is pumped to an arterial distal region of the arterial circulatory system. The pump is sutured to the descending thoracic aorta, such that the pump is in series with the natural blood flow through the circulatory system. The pump is controlled by an implantable power source and implantable controller. The

device further comprises a flow resistor (208, 85) that is capable of being controlled externally (see Figure 18). The pump comprises cannulae extensions (40, 42) that allow it to be attached to the circulatory system in a variety of positions.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Viole in view of Squitieri (US 6,102,884). Viole teaches the device substantially as claimed, but does not specifically teach that the device includes at least one additional outlet port for connection to a hemodialysis port. Squitieri teaches a blood shunt for transferring blood between vessels of the body, the system comprising supplemental ports allowing a hemodialysis system to be connected (see Figures 1-6). This configuration allows blood to be transferred between areas of the body in a similar manner as taught by Viole, but also provides a hemodialysis system to be easily connected through the skin when needed (figure 3). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the pumping device of Viole with the supplemental hemodialysis port of Squitieri in order to allow transferred blood to be easily subjected to hemodialysis when necessary, thereby preventing the need for a separate dialysis circuit attached to the body at a different location.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

//Leslie R. Deak//
Primary Examiner, Art Unit 3761
6 November 2008